

# **EXHIBIT H-1**

Except as modified below or otherwise agreed to the by the parties, search terms to be run in accordance with the terms and protocol entered by the Court on December 23, 2019 (Doc. 328).

<b><u>Standalone</u></b>	
<b><u>Original Term</u></b>	<b><u>Agreed Modification</u></b>
(*11025* or *18253* or *202223* or *203311* or *203820* or *20473* or *205347* or *20939* or *23491* or *24544* or *24873* or *29392* or *77530* or *78030* or *90483* or *90642* or *90866* or *91235*)	*200435* OR *091519* OR 77530 OR 077530 OR (77530 W/2 ANDA) OR anda077530 OR anda77530 OR anda_077530_ndma OR sanda077530 OR 90642 OR 090642 OR (90642 W/2 ANDA) OR anda090642 OR anda90642 OR anda_090642_ndma OR sanda090642 OR 91235 OR 091235 OR (91235 W/2 ANDA) OR anda091235 OR anda91235 OR anda_091235_ndma OR sanda091235
EIR or "establishment inspection report"	Move to Regulatory
OAI or "official action indicated"	Move to Regulatory
"voluntary action indicated"	Move to Regulatory
*diethylamine or "*diethyl amine"	Move to QA Testing
*dimethylformamide or DMF	Move "DMF" to QA Testing
(Form483) or (Form /3 483) or (483 /3 letter) or (483 /3 warn*) or (704 pre/3 b)	Move to Regulatory
carcin*	Move to Medical Conditions
FDA /10 warning	Delete Term
genotoxic*	Move to Regulatory
<b><u>Authors or Inspectors</u></b>	
<b><u>Original Term</u></b>	<b><u>Agreed Modification</u></b>
Barreto	(Barreto NOT W/2 Dan*)
<b><u>Regulatory</u></b>	
<b><u>Original Term</u></b>	<b><u>Agreed Modification</u></b>
("adverse event*" or AER) and (<drug name> or <solvents> or <facility names>)	Move to Medical Conditions
alert*	alert* /5 safe*
CFR or eCFR or "code of federal regulations" or USC or "United States Code" or "Title 21"	Run term as "W/500" rather than "AND"
inadequat*	Delete Term
inspect*	Run term as "W/500" rather than "AND" Run term as inspection* OR inspector* instead of inspect*
investigat*	Run term as "W/500" rather than "AND" Run term as investigation* OR investigator* instead of investigat*
major /3 change	Delete Term
(master /3 file) and (<drug name> or <solvents>)	Delete Term

minor /3 change	Delete Term
moderate /3 change	Delete Term
Monthly /3 update	Delete Term
observation*	Run term as "W/500" rather than "AND"
OOS or "out of spec*" or "out-of-spec"	Run term as "W/500" rather than "AND"
OOT or "out-of-trend" or "out of trend"	Run term as "W/500" rather than "AND"
PADER* and (<drug name> or <solvents> or <facility names>)	Do not run against "OR <regulatory modifiers>"
violat*	Run term as "W/500" rather than "AND"
warn*	Run term as "W/500" rather than "AND"

#### cGMP

<u>Original Term</u>	<u>Agreed Modification</u>
"cover up*" or coverup* or "cover-up"	("cover* up" or coverup or "cover-up" or "cover* ups" or coverups or "cover-ups")
delet* or destroy* or remov* or trash* or shred*	Run term as "W/500" rather than "AND" Modified to remove email footer language per agreement of the parties
<Term> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>) OR <regulatory modifiers> OR <inspect> OR <manufacturing modifiers> OR <medical modifiers> OR <facility names>)	<Term> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>) OR <regulatory modifiers> OR <inspect> OR <manufacturing modifiers> OR <facility names>)

#### QA Testing

<u>Original Term</u>	<u>Agreed Modification</u>
aberran*	Run term as "W/200" rather than "AND"
contami*	Run term as "W/500" rather than "AND"
detect*	Run term as "W/500" rather than "AND"
fail*	Run term as "W/500" rather than "AND"
problem*	Run term as "W/200" rather than "AND"
puri*	Run term as "W/200" rather than "AND"
recall*	Run term as "W/200" rather than "AND"
risk*	Run term as "W/200" rather than "AND"
toxic*	Run term as "W/200" rather than "AND"
validat*	Run term as "W/200" rather than "AND"

#### Manufacturing

<u>Original Term</u>	<u>Agreed Modification</u>
"PROCESS I" or "PROCESS II"	Do not run against the following Solvent terms: <ul style="list-style-type: none"><li>• acid*</li><li>• amlodipine*</li><li>• aqueous*</li><li>• HCT</li></ul>

	<ul style="list-style-type: none"> <li>• HCTZ</li> <li>• Hydrochlor*</li> </ul>
assessment*	Run term as "W/200" rather than "AND"
batch /5 records	batch /3 records
(certificate or COA)	Run term as "W/300" rather than "AND"
discrepanc*	Run term as "W/500" rather than "AND"
expir*	Run term as "W/500" rather than "AND"
quench*	Run term as "W/500" rather than "AND"
reagent*	Run term as "W/500" rather than "AND"
reclaim*	Run term as "W/500" rather than "AND"
recover*	Run term as "W/500" rather than "AND"
recyclcl*	Run term as "W/500" rather than "AND"
resal*	Run term as "W/500" rather than "AND"
resell*	Run term as "W/500" rather than "AND"
reuse*	Run term as "W/500" rather than "AND"
suppress*	Run term as "W/500" rather than "AND"
yield*	Run term as "W/500" rather than "AND"
error*	Run term as "W/500" rather than "AND" Modified to remove email footer language per agreement of the parties
temperature	Delete Term
<b>Medical Conditions</b>	
<u>Original Term</u>	<u>Agreed Modification</u>
blood*	Delete Term
death* or dead or fatal	death or deaths or dead or deadly or fatal
<b>Entities</b>	
<u>Original Term</u>	<u>Agreed Modification</u>
Ivax	Delete Term
distribut*	Delete Term
<b>Drug Names</b>	
<u>Original Term</u>	<u>Agreed Modification</u>
amlodipine*	Move to Solvents
HCT or HCTZ	Move to Solvents
detect*	Run term as "W/500" rather than "AND"
<b>Solvents</b>	
<u>Original Term</u>	<u>Agreed Modification</u>
*azide*	Index results and run as "OR" term without open-ended wildcard
*formaldehyde*	Index results and run as "OR" term without open-ended wildcard
acid*	Delete Term
<b>Regulatory Modifiers</b>	
<u>Original Term</u>	<u>Agreed Modification</u>

"Abbreviated New Drug Application" or ANDA	Do not run against cGMP
CDC or "Centers for Disease Control"	Do not run against cGMP
DEA or "Drug Enforcement Administration" or "Drug Enforcement Agency"	Do not run against cGMP
"Environmental Protection Agency" or EPA or USEPA or "US-EPA" or "1200 Pennsylvania Avenue"	Do not run against cGMP
NIH or "National Institutes of Health"	Do not run against cGMP
<b>Manufacturing Modifiers</b>	
<u>Original Term</u>	<u>Agreed Modification</u>
test*	Run term as "W/50" rather than "AND" with the following other terms: <ul style="list-style-type: none"> <li>• quality</li> <li>• validat*</li> <li>• impurit*</li> <li>• risk*</li> </ul> Run term as "W/200" rather than "AND" with the following other terms: <ul style="list-style-type: none"> <li>• remov*</li> <li>• fail*</li> <li>• detect*</li> <li>• residu*</li> <li>• suitab*</li> <li>• puri*</li> <li>• problem*</li> <li>• recall*</li> <li>• complain*</li> <li>• GMP*</li> <li>• unknown*</li> <li>• peak*</li> <li>• observation*</li> <li>• contami*</li> <li>• Chromato*</li> </ul>
<b>Medical Conditions Modifiers</b>	
<u>Original Term</u>	<u>Agreed Modification</u>
blood*	Delete Term
<b>Facility Names</b>	
<u>Identified Facility Name</u>	<u>Agreed Modification</u>
Actavis	Delete Term
*[FEI NUMBERS FOR FACILITIES]*	Index results and run as "OR" term without open-ended wildcard
Ha-Marpe	Ha-Marpe OR HaMarpe
Jerusalem	
JLM	

JLM OSD	
JE1	
Kiryat HaMada	
Malta	
Hal far	
Arrow	
Birzebbugia	Variations to be tested

#### **Specific Search String Modifications**

<u>Original String</u>	<u>Agreed Modification</u>
quality AND ((backup W/3 data) OR (impurit* AND degradant*) OR recall* OR residu* OR solvent* OR spike* OR test* OR (unknown W/3 peak) OR (unknown W/3 spike) OR (unknown W/3 impurit*) OR (unknown W/3 contamin*))	Run string as “W/200” rather than “AND”
validat* AND ((backup W/3 data) OR (impurit* AND degradant*) OR recall* OR residu* OR solvent* OR spike* OR test* OR (unknown W/3 peak) OR (unknown W/3 spike) OR (unknown W/3 impurit*) OR (unknown W/3 contamin*))	Run string as “W/200” rather than “AND”
risk* AND ((backup W/3 data) OR (impurit* AND degradant*) OR recall* OR residu* OR solvent* OR spike* OR test* OR (unknown W/3 peak) OR (unknown W/3 spike) OR (unknown W/3 impurit*) OR (unknown W/3 contamin*))	Run string as “W/200” rather than “AND”
(degradant* OR impurit*) AND ((backup W/3 data) OR (impurit* AND degradant*) OR recall* OR residu* OR solvent* OR spike* OR test* OR (unknown W/3 peak) OR (unknown W/3 spike) OR (unknown W/3 impurit*) OR (unknown W/3 contamin*))	(degradant*) AND ((backup W/3 data) OR (impurit* AND degradant*) OR recall* OR residu* OR solvent* OR spike* OR test* OR (unknown W/3 peak) OR (unknown W/3 spike) OR (unknown W/3 impurit*) OR (unknown W/3 contamin*)) (impurit*) W/250 ((backup W/3 data) OR (impurit* AND degradant*) OR recall* OR residu* OR solvent* OR spike* OR test* OR (unknown W/3 peak) OR (unknown W/3 spike) OR (unknown W/3 impurit*) OR (unknown W/3 contamin*))
(remov* OR trash* OR shred*) AND (Agency OR inspect* OR regulat*)	(remov* OR trash* OR shred*) AND (inspector* OR inspection* OR regulator*)
validat* AND ((backup W/3 data) OR (impurit* AND degradant*) OR recall* OR residu* OR solvent* OR spike* OR test* OR (unknown W/3 peak) OR (unknown W/3 spike))	Run string as “W/250” rather than “AND”

spike) OR (unknown W/3 impurit*) OR (unknown W/3 contamin*))	
complain* AND ((backup W/3 data) OR (impurit* AND degradant*) OR recall* OR residu* OR solvent* OR spike* OR test* OR (unknown W/3 peak) OR (unknown W/3 spike) OR (unknown W/3 impurit*) OR (unknown W/3 contamin*))	Run string as “W/250” rather than “AND”
residu* AND ((backup W/3 data) OR (impurit* AND degradant*) OR recall* OR solvent* OR spike* OR test* OR (unknown W/3 peak) OR (unknown W/3 spike) OR (unknown W/3 impurit*) OR (unknown W/3 contamin*))	Run string as “W/250” rather than “AND”
risk* AND ((backup W/3 data) OR (impurit* AND degradant*) OR recall* OR residu* OR solvent* OR spike* OR test* OR (unknown W/3 peak) OR (unknown W/3 spike) OR (unknown W/3 impurit*) OR (unknown W/3 contamin*))	Run string as “W/250” rather than “AND”
fail* AND ((backup W/3 data) OR (impurit* AND degradant*) OR recall* OR residu* OR solvent* OR spike* OR test* OR (unknown W/3 peak) OR (unknown W/3 spike) OR (unknown W/3 impurit*) OR (unknown W/3 contamin*))	Run string as “W/250” rather than “AND”
problem* AND ((backup W/3 data) OR (impurit* AND degradant*) OR recall* OR residu* OR solvent* OR spike* OR test* OR (unknown W/3 peak) OR (unknown W/3 spike) OR (unknown W/3 impurit*) OR (unknown W/3 contamin*))	Run string as “W/250” rather than “AND”